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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,437	04/10/2006	Sharad Magar	05558.0028.PCUS00	4300

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EXAMINER

PIHONAK, SARAH

ART UNIT	PAPER NUMBER
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1627

MAIL DATE	DELIVERY MODE
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11/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,437	Applicant(s) MAGAR ET AL.	
	Examiner SARAH PIHONAK	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2009 and 17 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32, 34-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 23-30 and 36 is/are allowed.
- 6) ☒ Claim(s) 31, 32, 34 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application, filed on 4/10/2006, is a 371 (national stage application) of PCT/EP03/50640, filed on 9/19/2003.

Priority

This application claims priority to Provisional Application No. 60/412308, filed on 9/20/2002.

Response to Arguments

1. Applicant's arguments, filed 6/30/2009, with respect to the rejection of claims 23-32 and 34-35 under 35 USC § 103(a) as being unpatentable over the WO 00/08015 publication, in view of Patani et. al., Chemical Rev., 96, pp. 3147-3176, 1996, have been fully considered and are persuasive. The rejection of claims 23-32 and 34-35 under 35 USC § 103(a) has been withdrawn.
2. Applicant's arguments, filed 6/30/2009, with respect to the rejection of claims 23-32 and 34 for nonstatutory obviousness type double patenting have been fully considered and are persuasive. The rejection of claims 23-32 and 34 for obviousness type double patenting has been withdrawn.
3. In telephone communications on 11/3/2009 and 11/16/2009, the examiner indicated the allowability of claim 23. It was also stated that some of the dependent claims were not commensurate in scope with independent claim 23. In response, the Applicants forwarded an amended set of claims on 11/17/2009.
4. The amended claims 23-30 and 36 are found to be free of the prior art. These claims therefore are allowable; a statement of reasons for allowance will be discussed further in this office action. However, claims 31, 32, 34, and 35 do

Art Unit: 1627

not find support from independent claim 23. Therefore, these claims are rejected under 35 USC § 112, second paragraph. This rejection will be discussed in depth further in this office action. Accordingly, this action is made **NON-FINAL**.

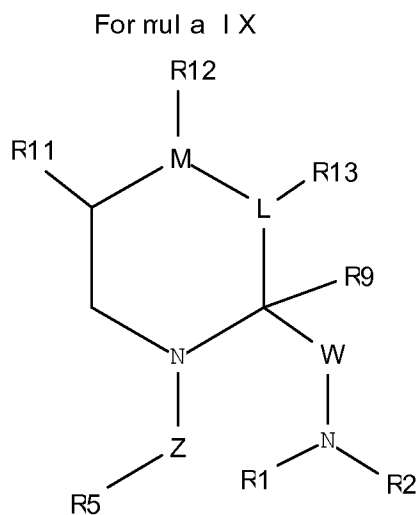
Claims 1-22 were previously withdrawn from consideration, as they are drawn to a non-elected invention.

5. Claims 23-32, and 34-36 were examined.
6. Claims 23-30 and 36 are allowed.
7. Claim 31-32, and 34-35 are rejected.

Statement of Reasons for Allowance

8. The following is a statement of reasons for the indication of allowable subject matter: There exists no prior art which teaches or suggests the compounds as claimed. The closest prior art is El Tayer et. al., WO 00/08015 patent publication. El Tayer et. al. teaches compounds of formula IX, shown below, as follicle stimulating hormone agonists which are useful for the treatment of infertility:

Art Unit: 1627



Where L and M = CH, N, O, S (but not both heteroatoms) (p. 7, lines 1-12);

W = (C=O), (NH(C=O)), (NH(C=O)CH₂), (C=NH), (C=S), SO₂, CH₂, or methylene substituted with one or more substituents (p. 3, lines 27-29);

Z = (C=O), (NH), (C=N), SO₂, or (C=O)NH, etc. (p. 4, lines 3-5);

R¹ and R⁵ = H, C₁₋₁₀ alkyl, aryl, C₃₋₇ heterocycle, etc. (p. 3, lines 9-19);

R² = H, C₁₋₆ alkyl, aryl, aryl substituted with one or more substituents, aryl groups fused with other aryl groups, heterocycles, etc. (p. 3, lines 20-26);

R⁹, R¹¹, R¹², R¹³ = H, C₁₋₈ alkyl, etc. (p. 7, lines 7-9, p. 4, lines 21-23, and p. 5, lines 1-8).

The compounds encompassed by formula IX as taught by El Tayer et. al. includes many compounds. However, there is no suggestion or teaching by El Tayer et. al. to select the claimed compounds over others. In particular, the claimed compounds are piperazine derivatives; while M is taught as possibly being selected from CH, N, O, or S, the compounds exemplified by El Tayer et. al. are not piperazine sulfonyl or piperazine sulfamoyl derivatives. There exists

Art Unit: 1627

no additional prior art or teaching to derive the claimed compounds from the compounds taught and exemplified by El Tayer et. al. Therefore, the claimed compounds are found novel and non-obvious over the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claim Rejections-35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 31, 32, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 31, which is a dependent claim of claim 23, recites the following compounds: {[3-(9-ethyl-9H-carbazol-3-yl-carbamoyl)-4-(thiophene-2-sulfonyl)-piperazine-1-carbonyl]-amino} acetic acid ethyl ester, 4-(thiophene-2-sulfonyl)-piperazine-1,3-dicarboxylic acid 3-[(9-ethyl-9H-carbazol-3-yl)-amide] 1-[[2-(1H-imidazol-4-yl)-ethyl]-amide; 4-(thiophene-2-sulfonyl)-piperazine-1,3-dicarboxylic acid 3-[(9-ethyl-9H-carbazol-3-yl)-amide] 1-[(3-imidazol-1-yl-propyl)-amide]; and

Art Unit: 1627

4-(thiophene-2-sulfonyl)-piperazine-1,3-dicarboxylic acid 3-[(9-ethyl-9H-carbazol-3-yl)-amide] 1-[(2-methoxy-ethyl)-amide]. The R^3 substituents for these compounds are respectively: 1-carbonyl-amino acetic acid ethyl ester; 1-[2-(1H-imidazol-4-yl)-ethyl]-amide; 1-[(3-imidazol-1-yl-propyl)-amide]; and 1-(2-methoxy-ethyl)-amide. The R^3 substituents for these compounds do not have support from independent claim 23. In particular, claim 23 does not cite that R^3 may contain ester substituents, alkoxy amino carbonyl groups, or alkyl amide groups substituted with heteroaryl groups. There is insufficient antecedent basis for this limitation in the claim. Claim 32, 34, and 35, which are dependent claims of claim 31, are also rejected for the reasons discussed above.

Conclusion

12. Claims 23-30 and 36 are allowed.
13. Claim 31-32, and 34-35 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH PIHONAK whose telephone number is (571)270-7710. The examiner can normally be reached on Monday-Thursday 8:00 AM - 6:30 PM EST, with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1627

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S.P.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1627